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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/870,009

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12/03/2004

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EXAMINER

SMITH, CAROLYN L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,009

Applicant(s)

KASHIMA ET AL.

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2004 and 06 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,8-12,15,17-27 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,8-12,15,17-27 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 9/1/04, has been entered.

Amended claims 5, 8, 11, 12, 15, and 30, filed 9/1/04, are acknowledged.

Claims herein under examination are 5, 8-12, 15, 17-27, and 30.

Claims Rejected Under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 5 recites the phrases "a portion, other than said gene portion, including no genetic information" which is vague and indefinite. It is unclear how a portion of DNA can be considered not to have genetic information when it is well known in the art that DNA is made up of nucleotides that are considered to be genetic information. Clarification of this issue, via

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clearer claim wording, is requested. Claim 30 is also rejected due to its direct dependency from claim 5.

Applicants state Examiner must use the definition of the term "genetic information" which is provided in the Application. Applicants state their definition of this phrase is on page 13, lines 3-6. This so-called definition is found unpersuasive as it does not clearly set forth the definition explicitly and with reasonable clarity, deliberateness and precision (MPEP 2111.01). When there is no explicit definition in the specification, the Examiner is instructed to look to the claims themselves and the context of the surrounding words, dictionaries, encyclopedias, treatises, and the prior art. The online Merriam-Webster dictionary defines "genetic" as "of or relating to genetics". The dictionary defines "genetics" as the genetic makeup and phenomena of an organism. The dictionary defines "information" as "knowledge obtained from investigation, study, or instruction". This phrase "genetic information" therefore can be reasonably and broadly interpreted to include all DNA by the mere presence of nucleotides which are encompassed by the phrase.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 5, 8-12, 15, 17-27, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Dollinger (P/N 5,451,505).

Dollinger discloses nucleic acids which are used as taggants that allows for subsequent identification of a substance, product identity (col. 1, lines 11-16 and 25-27) which represent watermark sequences, as stated in instant claim 30. Dollinger discloses a taggant as a nucleic acid that comprises a specific nucleotide sequence or composition (col. 2, lines 59-62). The term "genetic information" used in the claims lacks clarity, but the nucleotide sequence can be considered to be genetic information in the sense that it contains nucleotides. Dollinger discloses any substance may be used for tagging by treating the substance with a nucleic acid taggant (col. 1, lines 50-54). Dollinger discloses amplification of a nucleic acid sequence of a taggant, if present, to determine if the specific nucleic acid sequence is present (col. 1, lines 60-65) which represents a nucleic acid sequence including a taggant. Dollinger discloses nucleic acids that are covalently bound to the tagged material (including the taggant) (col. 2, lines 15-18) which is reasonably interpreted to be a gene portion and other portion (taggant), as stated in instant claim 5. Dollinger discloses tagging any substance with a nucleic acid taggant so that the nucleic acid attaches to the material (col. 1, lines 50-54). Dollinger discloses the nucleic acid taggant comprises a specific nucleotide sequence or a composition of specific nucleotides to facilitate tracing or determining the origin or source of a material (col. 1, lines 54-60 and col. 3, lines 7-8) which represents identifying a source and source identification information, as stated in instant claim 5. Dollinger discloses the nucleic acids can be either naturally occurring or synthetically derived (col. 2, lines 6-7) which represents a nucleotide sequence not naturally occurring in DNA (as stated in instant claims 5, 8, 11, 12, and 15), as well as not being naturally generated through

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gene mutation (as stated in instant claim 23) and intentionally designed (as stated in instant claim 8). Dollinger discloses the taggants are typically non-biologically functioning and are not part of a functional nucleic acid sequence operating in a living cell (col. 2, lines 62-65) which is reasonably interpreted to mean the taggant sequence does not affect transmission of biologically functional genetic information (portion including no genetic information) (as stated in instant claims 5, 8, 12, and 15). Dollinger discloses living organisms contain unique nucleic acid sequences either natural or artificially introduced (col. 2, lines 65-67), as stated in instant claim 12. Dollinger discloses using combinations of sequences and varying levels of specific sequences to identify the product, product's origin, the lot or batch, or an identifier for a unit of commerce (col. 3, lines 22-28) as well as using a sequence with multiple regions of specificity (col. 5, lines 9-11) which is reasonably interpreted to encompass multiple patterns at predetermined locations, as stated in instant claims 9, 10, 18, 19, and 20. The instant specification, page 1, second paragraph, defines "value-added genes" as having properties or values rated and levels assigned and creating added value to the gene. Dollinger discloses tracking animals and plants (gene bearing organisms) (col. 1, lines 17-19) which is reasonably interpreted to be determining product identity for cultivation or breeding purposes including value-added genes, as stated in instant claim 17. Dollinger discloses amplifying the sequence prior to detection via polymerase chain technology (col. 2, lines 3-5) which is reasonably interpreted to mean being copy tolerant, as stated in claim 21. Dollinger discloses the nucleic acids may be bound to solid support (devoid of genetic information and predetermined location) that is then mixed with the material being tagged (col. 2, lines 23-26), as stated in instant claims 15 and 26. Dollinger discloses that the nucleic acid may be covalently bound to any one or all of

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the components of a material comprised of different components (col. 2, lines 19-22) which represents embedding at random locations, as stated in instant claim 22. Dollinger discloses tagging methods involve detection and PCR technology where the nucleic acid must form duplexes with primers (complementary sequence) (col. 3, lines 41-47) and using hybridization techniques (col. 6, lines 3-20), as stated in claim 25. As it is unclear if instant claim 24 requires either a restriction enzyme identification or a promoter or both, Dollinger discloses promoters can be incorporated in the primers (col. 5, lines 47-51), as stated in claim 24. Dollinger discloses use of a taggant of a sequence complementary to the DQ α allele (gene) (col. 6, lines 55-56).

Thus, Dollinger anticipates the instant invention.

Applicants state the Dollinger reference does not teach or suggest instant claims 5, 8, 11, 12, and 15. This is found unpersuasive as these claims are broadly written such that a broad and reasonable interpretation of them includes the Dollinger reference, as described above.

Applicants state their claimed DNA may be used to identify the source of genetic information when DNA is copied by a third party. This statement is acknowledged, but this concept of third party copying is not included in the instant claims so that it is not imperative that the Dollinger reference mention these characteristics. Applicants state the Dollinger reference has nothing to do with DNA. This statement is found unpersuasive as Dollinger's recitation of nucleic acids is clearly a representation of DNA. The online Merriam-Webster dictionary defines DNA as "any of various nucleic acids...". Applicants state Dollinger discloses taggants is applied to the barrel of radioactive waste with a spray bottle. This is found unpersuasive as Dollinger discloses a plethora of ways to use the taggants. Dollinger discloses amplification of a nucleic acid

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sequence of a taggant, if present, to determine if the specific nucleic acid sequence is present (col. 1, lines 60-65) which represents a nucleic acid sequence including a taggant. Applicants arguments are found unpersuasive.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

November 29, 2004

Ardin H. Marschel 11/30/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER